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| APPLICATION NO.            | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|----------------------------|---------------------------------|----------------------|-------------------------|------------------|
| 09/960,706                 | 09/24/2001                      | William E. Munger    | 044921-5029-01          | 4547             |
| 9629 7:                    | 590 03/30/2005                  |                      | EXAMINER                |                  |
| MORGAN LEWIS & BOCKIUS LLP |                                 |                      | MORAN, MARJORIE A       |                  |
| WASHINGTO                  | LVANIA AVENUE NW<br>N. DC 20004 |                      | ART UNIT                | PAPER NUMBER     |
| ,                          |                                 |                      | 1631                    |                  |
|                            |                                 |                      | DATE MAILED: 03/30/2005 | 5                |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Application No.   | Applicant(s)  |  |
|-------------------|---------------|--|
| 09/960,706        | MUNGER ET AL. |  |
| Examiner          | Art Unit      |  |
| Marjorie A. Moran | 1631          |  |

**Advisory Action** Before the Filing of an Appeal Brief --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 07 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. 🔯 The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires 5 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): \_ 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. Tor purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. A The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). filed 3/7/05.

13. Other: See Continuation Sheet.

Marjorie A. Moran Primary Examiner

Art Unit: 1631

Continuation of 11. does NOT place the application in condition for allowance because:

35 USC 112 rejections:

In response to the argument that Tables 1 to 6 provide support for a database comprising any number of nucleic acids up to the total number of sequences in the table, applicant is reminded that particular ranges recited in the claims must find specific support in the originally filed disclosure. As set forth in the Final Office Action, specific support for a database comprising "at least 10", "at least 50" or "at least 70" different nucleic acid molecules is not found in the originally file disclosure. As applicant points to general support for "any" range or number of nucleic acid sequences, nut does not point to support for the particular ranges claimed, the examiner maintains that the claims recite new matter.

Applicant points to support in the originally filed specification for software for comparing sequences, therefore the rejection with regard to this limitation is hereby withdrawn. However, as the examiner maintains that the claims recite new matter with regard to the number of nucleic acid sequences comprised within the database, the rejection under 35 USC 112 is maintained.

35 USC 103 rejection

In response to the argument that MASLYN does not teach or suggest any aspect of BPH, applicant is reminded that MASLYN does teach a computer system comprising relational sequence information (col. 2) and software for allowing a user to compare query (sample) data to data in the database (col. 3, lines 4-10). As previously set forth, the sequence and data expression level information recited in the claims do not have a functional relationship with the hardware recited in the claims, and therefore do not distinguish the invention from the prior art in terms of patentability. The sequences and associated information are nonfunctional descriptive matter (see MPEP 2106), and do not functionally interact with the computer system itself; i.e. the sequences are not changed or transformed by the system or software nor is the computer system itself changed or transformed. The claimed software may be used with any set of nucleic acid sequence information without affecting the computer system itself. As set forth in In re Gulack, 703 F. 2d 1381 (217 USPQ 403,404), when there is no functional relationship between matter which is, by itself, non-statutory subject matter and a substrate (e.g. a computer), there is no reason to give patentable weight to the content (of the non-statutory subject matter). The sequences recited in the claims do not therefore distinguish the claimed system from the prior art in terms of patentability, and the examiner maintains that the claims are obvious.

In response to applicant's argument that "any rejection employing rational (sic) relying on nonfunctional descriptive material is improper" under 35 USC 103, applicant's attention is directed to MPEP 2106.VI, which provides direction for analysis under 35 USC 102 and 103 of claims reciting non-functional descriptive material as follows:

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. > In re Ngai, \_\_\_\_\_ F.3d \_\_\_\_, 2004 WL 1068957 (Fed. Cir. May 13, 2004).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the

claimed invention is simply a rearrangement of nonfunctional descriptive material.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As the prior art of MASLYN teaches software for comparing sample information to data in a database, as set forth above, neither the data itself nor the software distinguish the claims from the prior art, and the rejection is maintained

Continuation of 13. Other: It is noted that two pages of the IDS filed 3/7/05 are duplicative of earlier filed IDS's. In order to avoid confusion and possible duplication upon issuance of any patent, the copies of the IDS's filed 6/11/02 and 8/21/02 are included herewith, with all references crossed out. The references have been considered as part of the IDS filed 3/7/05.